

### Remarks

Claims 1, 8-19 and 21-23 are pending. Claims 2-7 and 20 have been canceled. Claims 1, 8, 10, 13-15, 17-19 and 21 have been amended. Amendments to Claims 1, 8, 13-15, 17-18, and 21 were made to comply with patent office rules regarding lack of antecedent basis in the claims. Other amendments to the claims are discussed below. New Claims 22 and 23 have been added. Support for the new claims can be found in the original claims and on page 6, lines 7-20 and Figures 1 and 2 of the specification. No new matter has been added by way of this amendment. Reconsideration and withdrawal of all outstanding objections and rejections is respectfully requested in light of these amendments and the following remarks.

### Claim Objections

The Examiner objected to Claims 2-12 as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicants have deleted Claims 2-7; thus rendering the objection moot for these claims. Applicants respectfully disagree with the Examiner's assertion that Claims 8-12 are in improper dependent form for failing to further limit the subject matter of a previous claim. Claim 1 has been amended so that it refers to an NS gene encoding an NS1 protein having an amino acid sequence comprising SEQ ID NO:5 and an NS2 protein having an amino acid sequence comprising SEQ ID NO:6. Claim 8 that depends from Claim 1 further limits the NS gene to the sequence set forth in SEQ ID NO:2. Claim 9 limits the host cells of Claim 1 to mammalian cells and Claim 10 further limits the mammalian cells of Claim 9 to cells suitable for preparing vaccines for use in humans. Claim 11 further limits the cells to the specific Vero cell line. Claim 12 limits the influenza virus of interest in Claim 1 to either human, avian, swine or equine.

Claims 19 and 20 were objected to because they are dependent upon rejected claim 18. Claim 18 has been amended to incorporate the limitation of the NS gene to one encoding an NS1 protein having an amino acid sequence comprising SEQ ID NO:5 and an NS2 protein having an amino acid sequence comprising SEQ ID NO:6 and the limitation of "other than A/England/1/53". Applicants believe Claim 18 is now in condition for allowance for reasons set forth below.

Applicants respectfully request reconsideration and withdrawal of these objections.

**35 USC § 112, paragraph 1 rejection**

The Examiner rejected Claims 1-12 based on the assertion that the specification does not reasonably provide enablement for a method for producing a high titer reassortant virus.

Applicants have removed "high titer" from Claim 1 as it is not needed to distinguish the present invention from the prior art nor to adequately describe the invention. However, the scope of the present invention still includes both viruses that may or may not exhibit high growth characteristics as demonstrated in the specification on page 18, lines 25 – page 19, line 30. Viruses that result from the methods of the present invention typically exhibit shorter half times to peak titer, but may not in every case.

Applicants request reconsideration and withdrawal of this rejection.

**35 USC § 112, paragraph 2 rejections**

The Examiner rejected Claim 1 as being indefinite for containing the term "high titer". The Examiner asserts that "high titer" is a relative term and is not defined in the specification. For the reasons pointed out above, Claim 1 has been amended so that "high titer" is no longer part of Claim 1.

The Examiner rejected Claim 10 as being indefinite for containing the term "cells approved for use in humans". Claim 10 has been amended to include the term "cells suitable for preparing vaccines for use in humans". Support for this amendment can be found on page 10, lines 20 – 25.

Claim 14 was rejected as being indefinite for containing the term "the HA and NA genes from an influenza virus of interest...". The Examiner asserts that it is unclear whether this includes the HA and NA genes from A/England/1/53. Claim 14 has been amended to show that the HA and NA genes from A/England/1/53 are excluded from the scope of the Claim. Support for this amendment can be found throughout the specification, specifically on page 5, lines 13-14 as well as the original claims.

Applicants respectfully request reconsideration and withdrawal of these 35 USC § 112, paragraph 2 rejections.

### **35 USC § 102 rejection**

Claims 13, 15, 17, 18 and 21 were rejected as being anticipated by Govorkova, EA et al, (1999) *The Journal of Infectious Diseases*. The Examiner asserts that the Govorkova reference inherently discloses the composition of the present claims even though Govorkova did not appreciate what was possessed at the time.

Applicants have revised Claims 13, 15, 17, 18 and 21 to claim an NS gene encoding an NS1 protein having an amino acid sequence comprising SEQ ID NO:5 and an NS2 protein having an amino acid sequence comprising SEQ ID NO:6. Applicants have further revised Claims 13, 15, 18 and 21 to exclude the HA and NA genes from A/England/1/53. By excluding the HA and NA genes from A/England/1/53 from the claims, the virus disclosed by Govorkova et al. is excluded from the scope of the claims and no longer anticipates Applicant's claimed compositions. Reconsideration and withdrawal of this rejection is respectfully requested.

Claim 17 refers to a kit that may be used to generate an influenza virus. The kit includes plasmids that contain the PB2, PB1, PA, NP and M genes from A/PuertoRico/8/34 and the NS gene from A/England/1/53. The kit provides a means for generating a virus, not the virus itself. Furthermore, no HA or NA genes are included in the kit. Govorkova et al. discloses a virus that contains eight genes, specifically 5 genes from A/PuertoRico/8/34 and 3 from A/England/1/53 and does not teach a kit for generating an influenza virus. Reconsideration and withdrawal of this rejection is respectfully requested.

### **35 USC § 103**

Claim 16 is rejected as being *prima facie* obvious in light of the Govorkova et al manuscript. The Examiner asserts that one of ordinary skill in the art would have been motivated to add an adjuvant to boost the immune response of influenza vaccines.

Applicants have revised Claim 15, from which Claim 16 depends, so that Claim 15 is no longer anticipated by Govorkova for reasons set forth above. Thus, the *prima facie* obviousness rejection is no longer valid. Reconsideration and withdrawal of this rejection is respectfully requested.

**Allowable Subject Matter**

The Examiner rejected Claim 14 under USC §112 ¶2 due to the language "the HA and NA genes of a virus of interest". Applicants have amended the Claim so that the HA and NA genes from A/England/1/53 are excluded from the scope of the Claim.

It is believed that all the objections and rejections have been obviated or overcome and the claims are in condition for allowance.

It is believed that no extensions of time are required. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 501968.

Respectfully submitted,

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